

Application No.: 09/847,945
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Attorney Docket No.: ABI1460-3
(071243-1317)

Amendments to the Claims/Listing of Claims

Please amend claims 1, 9, 17, 18, 25, 29 and 30, and cancel claims 2 and 19 as follows.
This listing of claims will replace all prior versions, and listings of claims in the application:

1. (Currently amended) A method for treating hyperplasia in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with a protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

2. (Cancelled).

3. (Original) A method according to claim 1 wherein said hyperplasia occurs in blood vessel neointima.

4. (Original) A method according to claim 1 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

5. (Original) A method according to claim 4 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

6. (Original) A method according to claim 1 wherein said composition is administered systemically.

7. (Original) A method according to claim 6 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

8. (Original) A method according to claim 1 wherein said composition is administered before, during or after the occurrence of said hyperplasia.

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9. (Currently amended) A method for reducing neointimal hyperplasia associated with vascular interventional procedure(s) in a subject in need thereof, said method comprising administering to said subject an effective amount of a composition comprising at least one amorphous drug in nanoparticle form, coated with a protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

10. (Original) A method according to claim 9 wherein said procedure comprises angioplasty, stenting or atherectomy.

11. (Original) A method according to claim 9 wherein said composition is administered before, during or after the vascular interventional procedure.

12. (Original) A method according to claim 9 wherein said composition is administered at the time of the vascular interventional procedure.

13. (Original) A method according to claim 9 wherein said effective amount falls in the range of about 0.01 mg/kg up to about 15 mg/kg for a human subject.

14. (Original) A method according to claim 13 wherein said administration of said composition is repeated over a dosing cycle between 1 day and 6 months.

15. (Original) A method according to claim 9 wherein said composition is administered systemically.

16. (Original) A method according to claim 9 wherein said composition is administered by deployment of a stent containing said at least one drug coated thereon.

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17. (Currently amended) A method to reduce proliferation and cell migration in a subject undergoing a vascular interventional procedure, said method comprising systemically administering to said subject before, during or after said procedure, a formulation comprising (i) an amorphous drug in nanoparticle form, wherein said drug that inhibits proliferation and cell migration, and (ii) a biocompatible protein to said subject before, during or after said procedure, wherein said drug is coated with said protein, and wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

18. (Currently amended). A composition for treatment of hyperplasia, said composition comprising (i) at least one amorphous drug in nanoparticle form, and (ii) protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

19. (Cancelled).

20. (Original) A composition according to claim 18 wherein said hyperplasia occurs in blood vessel neointima.

21. (Original) A composition according to claim 18 wherein said drug is a taxane or analog or homolog thereof, an epothilone or analog or homolog thereof, or a rapamycin or analog or homolog thereof.

22. (Original) A composition according to claim 21 wherein said taxane is paclitaxel.

23. (Original) A composition according to claim 18 wherein said composition is suitable for systemic administration.

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24. (Original) A composition according to claim 23 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

25. (Currently amended) A composition for reducing neointimal hyperplasia associated with vascular interventional procedure(s), said composition comprising at least one amorphous drug in nanoparticle form, coated with ~~and~~ a protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

26. (Original) A composition according to claim 25 wherein said procedure is angioplasty, stenting or atherectomy.

27. (Original) A composition according to claim 25 wherein said composition is suitable for systemic administration.

28. (Original) A composition according to claim 27 wherein administration is accomplished intra-arterially, intravenously, by inhalation, or orally.

29. (Currently amended) A method to reduce the toxicity of a drug that inhibits proliferation and migration of cells, said method comprising combining said drug, in amorphous form and in the form of nanoparticles, with a biocompatible protein, wherein said drug is coated with said protein, wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.

30. (Currently amended) A pharmaceutical formulation with reduced toxicity, said formulation comprising an amorphous drug in nanoparticle form, wherein said drug that inhibits proliferation and cell migration, wherein said drug is coated with a biocompatible protein, and wherein said drug is selected from the group consisting of an antineoplastic, an antiproliferative, an angiogenesis inhibitor, and mixtures of any two or more thereof.